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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,414	10/16/2001	Naomi Nakao	G30-001	4506

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EXAMINER

LANDREM, KAMRIN R

ART UNIT PAPER NUMBER

3738

DATE MAILED: 04/25/2003

24

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/978,414

Applicant(s)

NAKAO, NAOMI

Examiner

Kamrin R. Landrem

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 11-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☒ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group I, claims 1-10, in Paper No. 3 is acknowledged. The traversal is on the ground(s) that "while it is true that the method of Group II can be used for changing the shape of an organism for cosmetic surgery, it is not true that the method is not limited to the use of the product of Group I". This is not found persuasive because the product as claimed can be used in a materially different process of using that product, for example the product can be used an inflatable bladder/tissue expander used for harvesting graft tissue.

The requirement is still deemed proper and is therefore made FINAL.

Claims 11-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in Paper No. 3.

### ***Drawings***

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "28" has been used to designate both valves and conduits (see pg. 11, line 12). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Beginning with Claim 1, it is not clear what relationship “respective ones” establishes with the chamber.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-5, 9, and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Ledergerber (USPN 6,187,043).

Claim 1, with regards to a prosthesis comprising a body member made of biocompatible material, the body member have a plurality of inflatable chambers (94) and fluid guide element (98) enabling differential filling of said chambers, see all Figs and col. 9 line 59- col. 10, line 20.

Claim 2, with regards to plurality of conduits (98), see Fig. 18.

Claim 3, with regards to plurality of valves (106), see Fig. 18 and col. 9, lines 35-67.

Claim 4, with regards to terminal connector (102) mounted on body member and coupled with at least a plurality of said conduits, see Fig. 18.

Claim 5, with regards to radiopaque markers, see col. 9, lines 59-67.

Claim 9, with regards to form suitable for simulating the shape and size of a human breast, see col. 1, lines 13-15.

Claim 10, with regards to valves and use of compressive force, see col. 10 lines 1+.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ledergerber in view of).

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Ledergerber discloses a device composed of a biomaterial having a plurality of expandable chambers and fluid guide elements. Ledergerber discloses all of the claimed elements except for the particulars pertaining to the valves and the receiver/actuator for opening valves and controlling inflation of chambers. Conway et al teaches a prosthetic tissue expander in which multiple inflatable chambers are selectively inflated by use of actuator mechanisms that responds to insertion of syringe or other inflation device to open valves and permit inflation of respective chambers. Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized the inflation method of Conway in order to automatically and selectively inflate pre-selected expandable chambers of Ledergerber in order to create and match the desired size, shape and feel of the natural breast.

Claim 7, with regards to valves (24,28), chambers (18,16) and actuator mechanism (43), see Figs. 1-2 and col. 5, line 15- col. 6, line 47.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following USPN contain relevant material in regards to applicant's invention Fisher (5,496,367), Ledergerber (6,228,116), and Kung (6,508,756).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamrin R. Landrem whose telephone number is 703-305-8061. The examiner can normally be reached on 8:00-5:00, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for

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the organization where this application or proceeding is assigned are 703-308-3905 for regular communications and 703-308-3905 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Kamrin Landrem  
Examiner  
AU 3738

KRL  
April 18, 2003



David J. Isabella  
Primary Examiner